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Award Number: DAMD17-98-1-8306

TITLE: Facilitating Breast Cancer Genetic Counseling Through Information, Preparation and Referral: A Pilot Study Using the Cancer Information Service

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REPORT DATE: October 2002

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 2002	Final (8 Jun 98 -7 Sep 02)

4. TITLE AND SUBTITLE
Facilitating Breast Cancer Genetic Counseling Through Information, Preparation and Referral: A Pilot Study Using the Cancer Information Service

5. FUNDING NUMBERS
DAMD17-98-1-8306

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

Previous research shows that women often lack knowledge regarding the kinds of information required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. This pilot study developed an enhanced intervention to increase a woman's knowledge of: 1) the factors that determine a genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. Participants were 279 women who contacted the Atlantic Region of the National Cancer Institute's (NCI) Cancer Information Service (CIS) requesting information about risk for breast/ovarian cancer and/or information about risk assessment services and genetic testing. Women were randomly assigned to either the standard or enhanced intervention. The study, comparing the standard and enhanced interventions, tested the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing as well as her sense of preparation and intention to pursue such services.

14. SUBJECT TERMS: breast/ovarian neoplasms/psychology/genetics, communication, family relations, genes/BRCA1, genetic counseling/standards, genetic predisposition to disease, genetic screening, knowledge/attitudes/practice, patient education, risk factors

15. NUMBER OF PAGES
93

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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Introduction

Previous research shows that women often lack knowledge regarding the kinds of information required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. This pilot study developed an enhanced intervention, from material gathered during focus groups and structured interviews, to increase a woman's knowledge of: 1) the factors that determine a genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. The intervention was guided by the leading "information processing" theory, the Cognitive-Social Health Information Processing Model (C-SHIP) (Miller & Diefenbach, 1998). Participants were 279 women who contacted the Atlantic Region of the National Cancer Institute's (NCI) Cancer Information Service (CIS) requesting information about risk for breast/ovarian cancer as well as those women calling specifically for information about risk assessment services and genetic testing. Women were randomly assigned to either the standard intervention or the enhanced intervention. A randomized study in which the standard intervention was compared to the enhanced intervention tested the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing as well as her sense of preparation and intention to pursue such services.

Body

The identification of specific genes that predispose individuals and families to certain cancers is a milestone in medical research. Understanding the genetic basis of inherited cancers may lead to new approaches to treating and even preventing disease. For those in the general population who perceive themselves to be at risk, however, the identification of these cancer causing genes is as unsettling and unnerving as it is exciting and fraught with possibilities. The identification of the BRCA 1 and BRCA 2 genes were highly publicized and created a demand for genetic information and counseling. A review of articles dating from 1994 shows a growing interest in providing risk assessment, information, education and counseling about genetic risk and testing, options for 'at risk' individuals and surveillance recommendations for non-affected persons. Although public awareness has increased, women may not have the information they need, may have inaccurate risk perceptions (Hopwood, 2000) and may overestimate their risk for inherited disease (Iglehart, Miron et al. 1998). This project was designed to identify and address the needs of women who have concerns about their risks for inherited breast and/or ovarian cancers. In addition, for those women who intend to pursue high-risk counseling and/or genetic testing, the pilot aimed to educate and prepare them for that process.

Overview of the Project's Implementation

This project was divided into two phases. The first phase was a period of formative evaluation to inform the nature and design of the study as well as the content of the

interventions. This part of the project lasted eighteen months and included structured interviews and focus groups with women at actual or perceived high risk for inherited breast and/or ovarian cancer, cancer genetic counseling professionals and women from the lay population. It also included the development and implementation of an extensive training program for CIS Information Specialists to prepare them to respond to questions from callers. An Advisory Committee comprised of health care and health communications specialists reviewed the proposed interventions and made recommendations to strengthen the project overall. Finally, we worked with the Biostatistics Department at Fox Chase Cancer Center to design a Computer Assisted Telephone Interview system.

The second phase of the project was the recruitment to and conduct of the randomized trial comparing the standard and enhanced interventions, the subsequent two-week, two-month and six-month follow-up interviews and data analysis. We completed our final interviews in August 2002. The latest results are presented in this report.

Theoretical Model

While formulating the content area questions, we relied on the Cognitive-Social Health Information Processing (C-SHIP) theoretical model for guidance to ensure that as many key psychosocial factors associated with adherence to cancer-relevant health-protective behaviors were accounted for. The C-SHIP model was devised as a theoretical framework to help describe, explain, and predict human behavior in response to health-relevant threats that could have either health-enhancing or health-jeopardizing consequences (see Miller et al., 1996; Miller & Diefenbach, 1998). The model builds on the relevant cumulative findings of cognitive and social science as well as health psychology (e.g., Bandura, 1977; Carver & Sheier, 1981; Curry & Emmons, 1994; Leventhal, 1989). The C-SHIP model seeks to analyze systematically how individuals cognitively and affectively process information about their health, medical risks, and options. The model was launched with the intention of providing a theory-guided strategy and unifying approach for analyzing the psychosocial processes that underlie - and potentially undermine - health protective behavior, particularly in the oncologic context (see Lerman, Schwartz et al., 1996; Schwartz, Lerman et al., 1995), by building upon already existing social cognitive models (e.g., Lazarus & Folkman, 1984; Leventhal, 1989).

One priority during the development of the model was for it to serve a unifying function, capturing the range of cognitive-emotional processes that have been found to be operative in the face of health-relevant threatening life events (Miller & Diefenbach, 1998). These include: the individual=s encodings and construals, their expectancies about outcomes, their self-efficacy and control beliefs, the affects that become triggered, the individual=s health-relevant values and goals, and their self-regulatory competencies and skills, including the individual=s knowledge base and strategies for dealing with barriers - skills that must be both available and readily activated for successful adaptation. By identifying the cognitive-emotional processes that reduce psychosocial well-being and undermine physical heath during encounters with health threats, the model converges with, and complements, recently developed biobehavioral models of disease (e.g., Anderson et al., 1994). In more detail, the C-SHIP mediating units are:

Health-Relevant Encodings/Self-Construals. Strategies and constructs for appraising one=s own health and wellness, personal health risks and vulnerabilities, and illness and disease.

Health-Related Beliefs and Expectancies. Specific beliefs and expectations activated in health information processing. Includes expectancies about the disease (e.g., the individual=s optimistic/pessimistic beliefs about prevention and control options) and self-efficacy and control beliefs (e.g., the individual=s confidence about his/her ability to adhere to recommended screening, diagnostic, and treatment regimens).

Health-Relevant Affects/Emotions. Affective/emotional states activated in health-related information processing and behavioral responses (e.g., anxiety, depression, anger, intrusive and avoidant thinking).

Health-Relevant Goals/Values: Desired and valued health outcomes and their subjective importance (e.g., whether or not the individual believes that it is critical to be healthy) and goals for achieving health-relevant life projects (e.g., the individual=s intention to diet and exercise regularly).

Health-Relevant Self-Regulatory Coping Behaviors. Knowledge and strategies for dealing with barriers to disease prevention and control behaviors and for the constructions and maintenance of effective behavioral scripts over time. Includes coping skills for executing, maintaining, and adhering to long-term, health-protective behavioral and medical regimens (e.g., planning, self-reward, anxiety management).

The C-SHIP model, like the cognitive-affective meta-theory from which it is derived (Mischel & Shoda, 1995), also conceptualizes individuals as differing in two basic ways with respect to these mediating psychosocial processes. That is, individuals predictably differ in the ease with which they typically or chronically access relevant cognitions and affects, and in the pattern of interactions among the relevant cognitions and affects. Not only does the model, therefore, account for the effects of individual differences in singular cognitive-affective processes, but it also delineates the role played by the processing structure and dynamics within the system of cognitive-affective mediating variables (see Miller, Shoda et al., 1996). In our research (Miller, 1995; Miller, 1996), we have been exploring these signature patterns of interrelationships among the cognitive-affective mediating processes, and we have characterized them as *monitoring* versus *blunting*. Monitors, in the context of serious health threats, respond with a predictive cognitive-affective pattern that includes heightened affective distress, low perceptions of control and self-efficacy, and maladaptive coping responses, whereas blunters react with less affective distress, higher levels of perceived control and self-efficacy, and adaptive coping responses.

In utilizing the C-SHIP model, the content areas - and thus the enhanced intervention - addressed the individual=s encoding perceptions, beliefs and expectancies (e.g., about the pros and cons of testing, control), affect, and knowledge-based self-regulatory processes. Specific questions were designed with these factors in mind; for instance, the questions concerning familial risk endeavor to assist women to formulate accurate risk perceptions.

Formative Evaluation

Because of the relative scarcity of formalized, in-depth information about the informational and emotional needs of women concerned about their risks for inherited breast/ovarian cancer at the onset of this project, the first year of this pilot study necessitated a period of formative evaluation. In collaboration with counselors from the Family Risk Assessment Program at Fox Chase Cancer Center, we identified sample populations, both lay and professional, whom we targeted to gather information about what women knew, what they thought they knew and what they needed to know about cancer risks and before pursuing high risk counseling for inherited breast/ovarian cancer. Through a series of focus groups and structured interviews with women from the lay population, women at actual and perceived high risk and health professionals with a special interest in cancer and genetics, we yielded valuable, albeit conflicting, information about the needs of women pursuing high risk counseling and genetic testing. This information informed both the development of the enhanced intervention as well as the staff training outline.

Advisory Committee

Another key element in the development of the study intervention was gathering expert advice from professionals and advocates in the field. On October 5, 1999, a project advisory committee comprised of national and regional experts in breast cancer genetics, genetic testing and risk assessment met to review the draft interventions and promotional materials. Project staff presented an overview of the study, including results from the formative evaluation period, and solicited the committee's recommendations for any modification(s) of the proposed interventions and promotional fliers/brochures. Advisory Committee members, who had received drafts of the interventions and informed consent prior to the meeting, offered thoughtful and insightful reviews of the materials (see Appendix A for a list of Advisors). They offered advice on promotional materials as well as the interventions. We believe that having the benefit of expert advice strengthened, enhanced and validated the study instruments. Their keen observations and perceptions were invaluable in helping us refine and sharpen the interventions and promotional materials.

Study Interventions

The final versions of the study interventions (Appendices B & C) reflect content gathered from both the first year of formative evaluation of this as well as National Cancer Institute and American Cancer Society publications. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model (Miller, et.al., 1996, 1998), the interventions addressed participants' encoding perceptions, beliefs and expectancies, affect and knowledge-based self-regulatory processes.

The standard intervention included the following components

- Self reported perceptions about risks for breast and ovarian cancers
- Questions from the Lerman Worry Scale and the Breast Cancer Knowledge Scale (Lerman, et.al., 1994. Ondrusek, et.al., 1999.)
- Education about known risk factors for breast cancer
- Discussion about patterns of inheritance

- Referrals to high-risk programs in their areas, if the women would like them. (Those who request referrals are given them orally over the telephone and also are sent information about regional programs along with the standard literature.)
- Finally, women are asked about their current screening practices and demographic information.

The enhanced intervention included all of the above and, in addition

- Information about the hallmarks of inherited disease
- Specialists elicit a detailed family cancer history to be shared with the woman's primary health care provider.
- Women are also asked their knowledge and perceptions about the process, content and services involved in a formal risk assessment and genetic testing program, then educated about that which they did not mention.

Participants in both groups were sent the same NCI publications and factsheets. Those in the enhanced group were sent an additional publication, Understanding Gene Testing, as part of the randomization. In pilot testing, the interventions took anywhere from 15 to 20 minutes, depending on the randomization and whether or not the woman has many questions. In fact, many of the calls lasted longer than ½ hour because of the interaction between Specialist and caller. The consent process was modified to reflect the possibility of a lengthier interview.

Staff Training

Given the difficulty of the subject matter, multiple trainings were developed. They included sessions on basic genetics, cancer patterns and risk assessment, genetic counseling, genetic testing and informed consent, and understanding health behaviors. A separate session covered study logistics and familiarity with the computerized versions of the intervention (see Appendix D for an outline of the training curriculum). The training was completed over a 4-month period and subject matter experts conducted three of the sessions. Several of the resources that were initially identified and reviewed were also incorporated into the training. These resources served to reinforce specific concepts and made the training more interactive and interesting for staff. For example, video clips profiling the personal journeys of individuals and families confronting questions about genetic testing were included in the training on risk assessment and risk perception.

To evaluate the training, we developed pre- and post- tests to measure staff knowledge and attitude (Appendices E & F). There were 5 consistent knowledge questions and 2 attitudinal questions on both the pre and post- tests that were used for evaluation. The post-test also included 2 questions related to an interpretive exercise that measured the Information Specialists' ability to apply knowledge gained during training.

Computer Assisted Telephone Interview System

How best to implement, manage and coordinate the study was a subject of great import and interest for both the Behavioral and Psychosocial Medicine Program at FCCC and the CIS. The study required close coordination and constant monitoring to ensure data integrity and timely follow-up. In addition, assuring a constant flow of communication between the two programs demanded a shared system that could accommodate initial interventions and three series of follow-up interviews. Making use of current technology and the expertise available

at Fox Chase was a solution to the coordination and implementation question. Project staff decided to develop a Computer Assisted Telephone Interview, or CATI, system.

Ideally, the CATI system provides real-time data entry and automatically records study information in a confidential database. The information remains on file generating custom reports and permitting future analyses. The CATI can also ensure that researchers adhere to protocol as it has built-in skip patterns and can support multiple survey designs for the same project. We requested a CATI system that would begin with the Informed Consent. Contact information for those women who agreed to participate (i.e., names, addresses, and telephone numbers) was entered into the database, which automatically randomized women to the enhanced or standard intervention. Information Specialists conducted the interventions on-line. Once the data was completely entered, the system was able to generate custom letters including information on family cancer patterns for women in the enhanced group. It also generated a standard thank-you letter for participants in both groups. The system tracked the due dates for the follow-up interviews. A few days before the woman was due for a follow-up call her name appeared in the system. If she again agreed to consent, the appropriate follow-up (2-week, 2-month, or 6-month) was generated. For those women who were unable to complete a call, the system allowed for a "break-off" or, temporary holding database, that enabled us to maintain what data had already been collected and gave us what information we needed to contact the woman to complete the call.

The system allowed for different degrees of access. For instance, Information Specialists were only able to access the initial interview (which contained the Informed Consent). Researchers conducting follow-up interviews had access to those interviews as well as study data. Degrees of access were decided by project staff based on levels of responsibility and need.

Project staff met with FCCC programmers in August 1999 to discuss the design and feasibility of developing a CATI system for the study. The projected start date for the study was the middle of September. (We actually began recruiting women to the study in October.) While it was understood that the program would not be ready for implementation that soon, we hoped to have the initial interview functional by October. In fact, due to a number of obstacles, we did not have a functional system until January 2000. The programming was far too complicated to complete in just a few months. Also, there was a difference in the understanding of what was being requested, resulting in aspects of the application that did not suit the needs or expectations of the researchers and creating more work for the programmers. An unforeseen problem was the inability of an institutional server on which the application rests to support multiple users at the same time. That problem did not become apparent until the system was tested by an influx of calls in March 2000. Although no data was lost, Information Specialists had to revert to conducting the interventions on paper until the problem was first identified and then resolved. The server problem was addressed by upgrading the operating software. Programmatic problems are addressed as they arise.

A CATI system requires a great deal of planning, development and sophisticated programming. Because the interviews are so interconnected, small changes to one section

can require major changes in coding throughout. Inserting or deleting sections not only makes additional programming demands, it also necessitates changes in screen configuration. There may be challenges for the non-technical person in articulating needs and desires to the programmer. For the programmer, too, there may be disconnects between what the researcher is requesting and how that request is interpreted from a programming perspective. The development of a CATI system requires months of planning and preparation. For researchers who plan to use this technology to conduct their research, it is imperative to factor in sufficient time for development as well as usability testing. A CATI system also requires a network that can support it. The CIS computers were unable to run the application without error until they had more memory and an upgrade to a more stable network-operating platform (Windows NT). We have been fortunate to have in-house programmers and support from our institution. Their assistance and accessibility have been invaluable. Overall, the CATI system has proven to be a reliable, safe and secure repository of study data. Moreover, study data are easily retrieved by research staff for analysis and the system is able to interface with other applications (e.g., SPSS, Microsoft Excel, etc.).

Project Implementation

The Atlantic Region Cancer Information Service (CIS) recruited female callers to the *Facilitating Breast and Ovarian Cancer Genetic Counseling through Information, Preparation and Referral: A Pilot Study Using the Cancer Information Service* project through January 2002. Women calling the CIS who were over age 18 and who expressed concerns about their risks for breast or ovarian cancer and/or requested information about risk assessment services or genetic testing were asked to consent to the study (Appendix G). Those who agreed were randomized to receive a standard or enhanced intervention over the telephone. They were contacted and consented again at two weeks, two months and six months for follow-up telephone surveys (Appendices H, I & J).

Cancer Information Specialists gained consent and conducted the baseline interviews using the Computer Assisted Telephone Interview (CATI) system designed for the project. Those who agreed to participate were automatically randomized to receive the standard or enhanced intervention. The data were stored in the CATI system that was shared by the CIS and the Psychosocial and Behavioral Medicine Program at Fox Chase Cancer Center (FCCC). Researchers from that program were then able to access participants' information for follow-up interviews.

The CIS and the Psychosocial and Behavioral Medicine Program worked closely with the Biostatistics Department at FCCC to assure smooth and timely implementation of the interventions, accurate retention and transmission of research data within the CATI system and extrapolation of data to the Statistical Package for the Social Sciences (SPSS). Any problems that arose with the database were minor performance issues that were readily identified and resolved. The CATI system proved to be a dependable and easily accessible method of gathering, maintaining and collating data.

Baseline Interviews

Since the inception of the project, CIS Information Specialists introduced the study to 452 eligible callers; 329 of whom (73%) agreed to participate. Fifty (11%) women had to "break

off" the initial call before the intervention was complete. Reasons for breaking off include insufficient time, call too stressful or personal, and lack of interest. Of those who agreed to participate, 279 (85%) completed the baseline interventions. Randomization has been successful, with 127 women receiving the standard intervention and 152 women receiving the enhanced intervention.

Interviews are conducted and data entered using the web-based CATI system designed for the project. Analysis of length of time per call demonstrated more time, on average, than original estimates. Those estimates were based on the time it took to go through the interviews with limited questions from the participants. Study subjects, however, have been active participants in the interviews, and the time to complete the call has increased accordingly. The Informed Consent was revised to reflect more accurately the time commitment for the initial baseline interview. Instead of the fifteen to twenty minutes previously reported, the consent now reads fifteen to thirty minutes (Appendix A).

We originally estimated that we would need to recruit 275 women during a 16-month accrual period. With an anticipated 90% participation rate and an 80% response rate to the two-month follow-up interview (figures based on previous studies conducted within the CIS), we calculated a final sample size of 200 participants (100 per intervention group). A reassessment of those figures indicated a need to increase the number of women recruited based on a study participation rate of 73% and an overall completion rate of almost 62%. Accordingly, we requested and were granted an unfunded extension to continue recruiting women to the study so as to assure statistical validity.

Follow-up Interviews
Research staff from the Psychosocial and Behavioral Medicine Program of the Fox Chase Cancer Center conducted follow-up interviews. They use the CATI system to track outstanding interviews as well as to conduct the follow-up calls.

Participant Attrition - Rates and Reasons: Overall, CIS Information Specialists introduced the study to 452 eligible callers, of whom 329 (73%) agreed to participate. Fifty of those participants (15%) never completed the baseline interviews, citing lack of interest as their primary reason for withdrawal. Thus, we are able to retain 85% of participants through the baseline interview. The likelihood of withdrawal during the baseline assessment is not related to study condition.

From the 279 women who completed baseline assessments, 200 2-week follow-ups were completed. We were unable to reach 66 participants after attempting calls an average of 13 times, and 13 women dropped out of the study at this point. Our completion rate for the 2-week follow-up is 72%. The women who could not be reached for the 2-week contact were retained in the study for subsequent assessments.

From the 266 women who were retained in the study after the 2-week follow-up, 199 2-month follow-ups were completed. We were unable to reach 52 participants after attempting calls an average of 12 times, and 15 women withdrew from the study at this point. Our

completion rate for the 2-month follow-up is 75%. The women who could not be reached for the 2-month contact were retained in the study for subsequent assessments.

Finally, from the 251 women retained in the study after the 2-month follow-up, we completed 182 six-month interviews. Thirteen women dropped out of the study at the 6-month assessment point and 56 women were not available for the assessment (i.e., we were unable to contact them after an average attempt of 13 calls). Our completion rate for the 6-month follow-up is 72%. We were unable to complete any follow-up calls with 9 participants, bringing the total number of withdrawals or equivalent to 50.

Therefore, we have had a total of 50 women withdraw from the study (i.e., 41 withdrawals and 9 participants we were unable to contact) - an attrition rate of 18%. There has not been differential attrition across the study conditions. Reasons given for withdrawing from the study include: participant no longer interested, personal health reasons, believing that there was nothing to gain from participation, family health problems, not wanting to think about cancer risk and, a disconnected phone. Overall, these data indicate that we: 1) retained participants in the study sufficiently to meet our recruitment goals, and 2) there was no differential attrition across study conditions.

The following table summarizes the follow-up interviews to date.

Table 1. Summary of Follow-up Interviews

Summary of Follow-up Interviews			
	2-week follow-up n=279	2-month follow-up n=266	6-month follow-up n=251
Number Completed	200 (72%)	199 (75%)	182 (73%)
Number not reached (no answer) *Average number of attempts*	66 (24%) *13*	52 (20%) *12*	56 (22%) *13*
Number of Withdrawals	13 (5%)	15 (6%)	13 (5%)
Number never able to be reached for follow-up *Adjusted six-month withdrawal* *Total number of withdrawals*			9 (3%) 22 (8%) 50 (18%)
Retention Rate	95%	90%	82%

Summary of the Implementation

At the time of submission of this report we randomized 329 women to either the standard or enhanced treatment condition. Fifty (50) women withdrew from the study after randomization; lack of interest was the primary reason for withdrawal. Thus, 279 baseline interviews were completed. From this sample, 200 2-week interviews were completed; 199 2-month interviews were completed, and 182 6-month interviews were completed. Our attrition rate is approximately 18%.

For this final report, our analyses focused on accomplishing 4 specific aims, as outlined below.

Aim 1. To describe the overall sample of participants in terms of: 1) background variables (i.e., demographic variables, reason for calling the CIS, medical status, and past utilization of risk assessment services), 2) screening variables (e.g., mammography, readiness to pursue risk assessment and genetic testing), 3) knowledge concerning breast/ovarian cancer risk factor (e.g., age), 4) perceived breast/ovarian cancer risk, 5) emotional distress related to perceived breast/ovarian cancer risk, 6) overall and specific knowledge concerning breast/ovarian cancer risk assessment and genetic testing procedures, and 7) immediate responses to the intervention (i.e., satisfaction with information received, likelihood of referring others to the CIS. These analyses will allow for the preliminary assessment of the external validity of the present study.

Aim 2. To examine any and all potential differences between enhanced intervention participants and standard intervention participants in order to verify that the randomization methods have been successful in distributing any possible confounding or extraneous variables evenly across the two study conditions. Specifically, we assessed potential differences between treatment conditions in terms of the 7 types of variables listed in Aim 1.

Aim 3. To examine rates of, and reasons for, participant attrition in order to verify our ability to retain participants in the study, assess whether there is differential attrition across study conditions, and substantiate our ability to meet our recruitment goals.

Aim 4. To highlight baseline levels of knowledge concerning breast/ovarian cancer risk assessment and genetic testing, and breast/ovarian cancer etiology and prevention. This analysis was intended to offer to the Review Committee further data from our population supporting the need for the development and refinement of an enhanced intervention that would prepare women as they pursue information and services for breast/ovarian cancer risk assessment and genetic testing.

Summary of Baseline Data

The results of our analyses to address each aim described above are delineated below in the respective sections. The Statistical Package for the Social Sciences (SPSS) was used for the

statistical analyses. The specific procedures used to address the respective aim are described within the respective sections.

Overall Sample Description at Baseline: For ease of presentation and evaluation, the results are presented in tabular format (see Tables 2-8). Means and standard deviations were calculated for interval or ratio scale variables and frequency distributions were computed for nominal or ordinal scale variables.

Table 2. Overall Description of the Entire Sample (N = 279). *

Grouping Variable		
Variable	*Frequency*	**Percentage**
Treatment Condition		
Enhanced	152	54.5%
Standard	127	45.5%
Background Variables		
Variable	*Frequency or Mean*	**Percentage or Standard Deviation**
Age	46.32 years	12.28 years
Education		
Some High School	10	4%
High School Grad	65	25.5%
Some College	69	27%
College Grad	69	27%
Post-graduate	42	16.5%
Race/Ethnicity		
Asian	2	1%
African American	14	5%
Hispanic	3	1%
Native American	4	2%
Caucasian	227	89%
Other	6	2%
Reason for Calling CIS		
For breast cancer risk information	208	76%
For ovarian cancer risk information	32	12%
For both breast and ovarian cancer risk information	34	12%
Cancer Diagnosis		
Yes	64	23%
No	213	77%
Past Use of Risk Assessment Services		
Yes	34	12%
No	242	88%

Table 3. Screening Variables

Screening Variables

Variable	*Frequency*	Percentage
Mammography		
Once every few months	6	2%
A couple time per year	22	8%
Once a year	162	59%
Once every few years	39	14%
Almost never	10	4%
Never	36	13%
Breast Self-Exam		
More than once per week	22	8%
At least once per week	30	11%
A couple times per month	40	14.5%
At least once per month	107	39%
A few times per year	34	12%
At least once per year	5	2%
Almost never	18	6.5%
Never	19	7%
Pelvic Exam		
Yes	56	20%
No	223	80%
Trans-vaginal Ultrasound		
Yes	16	6%
No	263	94%
CA125		
Yes	18	6%
No	261	94%
Readiness to Pursue Risk Assessment/Genetic Testing		
Precontemplation	60	22%
Contemplation	131	47%
Preparation	74	26%
Action	13	5%
Preparedness to Pursue Risk Assessment/Genetic Testing		
Not at all	41	16%
Somewhat	105	40%
Quite	54	21%
Very	59	23%
Request for Referral to a Risk Assessment/Genetic Testing Program		
Yes	163	60%
No	110	40%

Table 4. Perceived Risk Factors

Perceived Risk Factors

Variable "What things do you think contribute to your risk for breast/ovarian cancer?"	Frequency	Percentage
Age		
Yes	35	13%
Not Mentioned	244	87%
Early Menarche		
Yes	21	8%
Not Mentioned	258	92%
Late Menopause		
Yes	8	3%
Not Mentioned	271	97%
Family History/Genetics		
Yes	238	85%
Not Mentioned	41	15%
Personal History of Cancer		
Yes	44	16%
Not Mentioned	235	84%
Pregnancy		
Yes	38	14%
Not Mentioned	241	86%
Previous Breast Biopsies		
Yes	35	13%
Not Mentioned	244	87%
Lifestyle		
Yes	97	35%
Not Mentioned	182	65%
Diet		
Yes	54	19%
Not Mentioned	225	81%
Smoking		
Yes	52	19%
Not Mentioned	227	81%
Exercise		
Yes	13	5%
Not Mentioned	266	95%
Alcohol		
Yes	11	4%
Not Mentioned	268	96%

Stress		
Yes	9	3%
Not Mentioned	270	97%
Personal Health History		
Yes	40	14%
Not Mentioned	239	86%
Hormone Replacement Therapy		
Yes	20	7%
Not Mentioned	259	93%
DES		
Yes	1	0.1%
Not Mentioned	278	99.9%
Abortion		
Yes	2	0.1%
Not Mentioned	277	99.9%
Oral Contraceptives		
Yes	13	5%
Not Mentioned	266	95%
Environment		
Yes	32	11%
Not Mentioned	167	89%

Table 5. Perceived Breast/Ovarian Cancer Risk

Perceived Breast/Ovarian Cancer Risk		
Variable	*Frequency*	**Percentage**
Breast cancer risk vs. other women the same age		
Very low	4	2%
Somewhat low	25	9%
Average	51	19%
Somewhat high	108	41%
Very high	78	29%
Ovarian cancer risk vs. other women the same age		
Very low	25	11%
Somewhat low	48	21%
Average	66	29%
Somewhat high	65	29%
Very high	22	10%
Breast cancer risk vs. other women the same age with family history		
Very low	10	4%
Somewhat low	27	10%
Average	68	26%
Somewhat high	100	38%
Very high	59	22%
Ovarian cancer risk vs. other women the same age with family history		
Very low	26	11%
Somewhat low	51	22%
Average	80	35%
Somewhat high	47	21%
Very high	26	11%

Table 6. Emotional Distress Concerning Cancer Risk

Emotional Distress Concerning Cancer Risk		
Variable	*Frequency*	**Percentage**
Have thoughts about getting breast cancer		
Not at all	54	20%
Sometimes	86	31%
Often	69	25%
A lot	67	24%
Have thoughts about getting ovarian cancer		
Not at all	161	60%
Sometimes	59	22%
Often	23	9%
A lot	23	9%
Thoughts about breast cancer risk affect mood		
Not at all	140	51%
Sometimes	72	26%
Often	35	13%
A lot	29	10%
Thoughts about ovarian cancer risk affect mood		
Not at all	199	73%
Sometimes	50	18%
Often	17	6%
A lot	8	3%
Thoughts about breast cancer risk affect daily activities		
Not at all	218	79%
Sometimes	41	15%
Often	10	3%
A lot	8	3%
Thoughts about ovarian cancer risk affect daily activities		
Not at all	246	89%
Sometimes	21	8%
Often	6	2%
A lot	2	1%

Table 7. Knowledge Variables

Knowledge Variables		
Variable	*Frequency or Mean*	**Percentage or Standard Deviation**
Rating of overall knowledge about risks and assessment		
Not at all knowledgeable	23	8%
Not very knowledgeable	146	53%
Somewhat knowledgeable	79	29%
Very knowledgeable	27	10%
Many women who do not have any of the known risk factors still get breast cancer		
Correct	259	93%
Incorrect	20	7%
Over a lifetime, 1 out of 8 women will develop breast cancer		
Correct	240	86%
Incorrect	39	14%
Women who are over 50 years of age are more likely to get breast cancer than are younger women		
Correct	202	72%
Incorrect	77	28%
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer		
Correct	188	67%
Incorrect	91	33%
Early detection means a greater chance of surviving breast cancer		
Correct	279	100%
Incorrect	0	0%
Women over age 40 should have mammograms at least every two years		
Correct	217	78%
Incorrect	62	22%
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer		
Correct	77	28%
Incorrect	202	72%
A woman can inherit breast cancer gene mutations from her father		
Correct	158	57%
Incorrect	121	43%

Most women who develop breast cancer do not have a family history of the disease		
Correct	164	59%
Incorrect	115	41%
Ovarian cancer and breast cancer in the same family can be a sign of hereditary breast cancer		
Correct	239	86%
Incorrect	40	14%
Testing for breast cancer gene mutations can tell a woman if she has breast cancer		
Correct	167	60%
Incorrect	112	40%
Men cannot inherit breast cancer gene mutations		
Correct	238	85%
Incorrect	41	15%
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer		
Correct	192	69%
Incorrect	87	31%
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test		
Correct	61	22%
Incorrect	218	78%
One of the advantages of risk assessment and genetic testing is that, finding out your risk, can help you make decisions about pursuing risk reduction options, such as surgery and medications		
Correct	268	96%
Incorrect	11	4%
There are no real disadvantages to pursuing risk assessment and genetic testing		
Correct	154	55%
Incorrect	125	45%
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer		
Correct	156	56%
Incorrect	123	44%
Knowledge Total Score (Out of 17)	11.68	2.2

Table 8. Responses to the CIS

Responses to the CIS		
Variable	*Frequency*	**Percentage**
Level of satisfaction with information received		
Not at all	0	0%
A little	5	2%
Moderately	18	6%
Quite a bit	75	28%
Very much	172	64%
Degree to which they will recommend the CIS to others		
Definitely no	1	0%
Probably not	0	0%
Maybe	9	3%
Probably yes	230	85%
Definitely yes	32	12%

Note. * indicates that frequencies do not always total 279, since participants may have omitted answering particular questions.

Summary of Analysis

In order to assess for the presence of any potential extraneous or confounding variable, we examined differences between the study conditions in terms of baseline measures described in Aim 1. For ordinal, interval, or ratio data (e.g., age, rate of mammography, perceived risk, emotional distress, level of satisfaction) the ANOVA procedure was used, with the two intervention groups serving as the levels of the independent variable. For nominal data (e.g., ethnicity, perceived risk factors, knowledge items), the chi-square test of association procedure was utilized.

With regard to all background variables (i.e., demographic variables, reason for calling, cancer history, past use of risk assessment services), there were no significant differences between the study conditions (i.e., all p's > .05), with the exception of age at baseline (average age, enhanced group – 47; average age, standard group – 44, p=. 045). Likewise, there were no significant differences between study conditions with regard to baseline measures of: 1) breast and ovarian cancer screening, readiness to pursue risk assessment and genetic testing, and degree to which participants felt prepared to pursue risk assessment and genetic testing; 2) level of endorsement of the CIS (i.e., satisfied with information received, recommend CIS to others), 3) degree of perceived risk of developing breast or ovarian cancer, 4) level of emotional distress concerning developing breast or ovarian cancer, and 5) participant's total level of knowledge about breast and ovarian cancer and about risk assessment procedures (i.e., all p's > .05). Likewise, there were no significant differences between enhanced and control participants with regard to the endorsement of specific breast and ovarian cancer risk factors (i.e., all p's > .05). Finally, baseline levels of correct responses to the true or false assessment of knowledge about breast and ovarian cancer risk

assessment and genetic testing and etiology were contrasted across the two study conditions. No significant differences were detected.

To examine the research question concerning the effect of the intervention over time on self-reported intention to pursue genetic testing/risk assessment, knowledge about genetic testing/risk assessment, preparation to genetic testing/risk assessment, and satisfaction with the Cancer Information Service (CIS), based on objective breast/ovarian cancer risk, two-by-two factorial ANOVAs were conducted. Women who reported having pursued risk assessment in the past were removed from the analysis. Subsequent analysis of baseline differences between groups with the exclusion of past participants no longer demonstrates a significant difference in age ($p=.077$); however, there is a difference in intention to pursue risk assessment services ($p=.032$). We controlled for this difference in intention to pursue at baseline by using difference scores.

Three variables were created for each of the 4 dependent variables to represent the change in the dependent variable from baseline to the 2-week follow-up, the 2-month follow-up, and the 6-month follow-up, respectively. These "difference" scores for each variable and for each time point were constructed such that higher scores represent greater change in the measure over time. Thus, 12 ANOVAs were conducted, 3 for each time-point for the 4 dependent variables. In addition, since the knowledge measure was comprised of the summation of 17 items, we conducted a principal components analysis with varimax rotation in order to explore whether specific scale components were identifiable. This analysis indicated that 2 scale components were evident: Knowledge Component A (items 8, 10, and 12) and Knowledge Component B (items 4, 9, and 11). Again, difference scores were computed for these Knowledge Components to reflect the change from baseline to 2-weeks, 2-months, and 6-months, respectively, in these components. Two-by-two ANOVAs were conducted to examine differences in the 6 measures of knowledge (2 Components and 3 time-points). For all ANOVAs, women who reported that they had participated in risk assessment/genetic testing were excluded and age was included as a covariate.

Intention. For the 3 ANOVAs for intention to pursue genetic testing/risk assessment, there were no differences (either main effects or interaction effects) across the groups for the 2-week and 2-month time-points ($p > .05$). However, at 6-months there was a significant interaction effect for intention to pursue genetic testing/risk assessment ($F[1, 113] = 8.96$, $p < .05$). In particular, there was a significant increase in intention to pursue genetic testing/risk assessment after 6-months for women at high risk only in the enhanced intervention ($M = 4.2$), compared to high risk women in the standard intervention ($M = 3.7$); conversely, women at average risk in the enhanced intervention exhibited a decrease in intention to pursue genetic testing/risk assessment at 6-months ($M = 3.1$), compared to average risk women in the standard intervention ($M = 3.8$).

Knowledge. For the 3 ANOVAs for knowledge about genetic testing/risk assessment, there was a significant main effect for risk group (average versus high) at the 2-week follow-up ($F[1, 137] = 7.01$, $p < .05$) and at the 2-month follow-up ($F[1, 133] = 4.79$, $p < .05$). In particular, regardless of treatment condition, women with average risk showed a greater increase in knowledge about genetic testing/risk assessment at 2-weeks ($M = 5.9$), compared

to women at high risk for breast/ovarian cancer (M = 4.6). Likewise, at 2-months, women with average risk showed a greater increase in knowledge about genetic testing/risk assessment (M = 5.9), compared to women at high risk for breast/ovarian cancer (M = 4.8). There were no differences, either main effects or interaction effects, at the 6-month time-point for knowledge about genetic testing/risk assessment.

Finally, for the 6 ANOVAs conducted for the 2 Knowledge Components that emerged from the factor analysis, only one significant effect was detected. For Knowledge Component A, there was a significant interaction effect detected at the 2-month time-point ($F[1, 133] = 4.00$, $p < .05$). In particular, there was a significant increase in Knowledge Component A after 6-months for women at high risk only in the standard intervention (M = 3.7), compared to high risk women in the enhanced intervention (M = 3.3); conversely, women at average risk in the standard intervention exhibited a decrease in Knowledge Component A after 6-months (M = 3.2), compared to average risk women in the enhanced intervention (M = 3.4).

Preparation. For the 3 ANOVAs for preparation to pursue genetic testing/risk assessment, there were no differences, either main effects or interaction effects, at the 2-week and 2-month time-points. However, at 6-months there was a significant interaction effect for preparation to pursue genetic testing/risk assessment ($F[1, 85] = 6.12$, $p < .05$). In particular, there was a significant increase in preparation to pursue genetic testing/risk assessment after 6-months for women at high risk only in the enhanced intervention (M = 3.5), compared to high risk women in the standard intervention (M = 2.6); conversely, women at average risk in the enhanced intervention exhibited a decrease in preparation to pursue genetic testing/risk assessment at 6-months (M = 2.9), compared to average risk women in the standard intervention (M = 2.6).

Satisfaction. For the 3 ANOVAs for satisfaction with the CIS, there were no differences, either main effects or interaction effects, at the 2-week, 2-month, and 6-month time-points ($p > .05$). This finding, or lack thereof, has bearing on the feasibility of implementing the enhanced intervention as the standard of service for women at high risk for breast cancer calling the CIS for information about inherited risk for cancer, risk assessment services and/or genetic testing. The enhanced intervention was considerably lengthier than the standard, which might have proven burdensome and unsatisfactory to participants. Despite its length, however, participants indicated high levels of satisfaction with both the service provided by the CIS and the information received. The fact that the enhanced intervention increased intention and preparation to pursue risk assessment services in those high-risk women most in need of such services and was satisfactory to them suggests that it may be feasible to implement.

Analyses of Study Outcomes – Attentional Style

A further aim was to examine the moderating role of attentional style (i.e., high monitors – who typically scan for and attend to health-related threats vs. low monitors – who typically distract from and ignore health cues) on the interventions impact on outcomes of interest, based on objective breast/ovarian cancer risk. Toward this end, further ANOVAs are being conducted, adding monitoring attentional style as an additional factor of interest.

A particular focus of interest is on the moderating impact of monitoring on satisfaction. At the 6-month follow-up, a significant 3-way interaction was detected for satisfaction with the CIS ($F [1,103] = 11.61$, $p=.001$). As expected, among women at average risk, high monitors had greater satisfaction with CIS when receiving the enhanced intervention as compared to standard care. Conversely, low monitors at average-risk displayed greater satisfaction when they received the standard care condition as compared to the enhanced intervention. This is the pattern of results typically obtained in the literature for high vs. low monitors, since high monitors generally fare better with voluminous amounts of detailed risk-related information. A different pattern emerged for high-risk women. High monitors reported greater satisfaction when they received standard care than with the enhanced protocol, while low monitors at high-risk were more satisfied when receiving the enhanced intervention over standard care. This finding suggests that when the risk is more intense, voluminous information may be too threatening and not sufficiently reassuring for high monitors. Conversely, increased risk may motivate low monitors to attend to (rather than ignore) their situation, and so they are more satisfied with enhanced counseling. Interestingly, this effect emerged over time. We are continuing to explore the role of monitoring in ongoing analyses.

Key Research Accomplishments

- 279 women recruited to the study who completed baseline interviews
- Completed Two-week Interviews – 200
- Completed Two-month Interviews – 199
- Completed Six-month Interviews – 182
- Completed Interviews at all time points – 128
- There was a significant increase in intention to pursue genetic testing/risk assessment after 6-months for women at high risk only in the enhanced intervention compared to high risk women in the standard intervention
- There was a significant increase in preparation to pursue genetic testing/risk assessment after 6-months for women at high risk only in the enhanced intervention compared to high-risk women in the standard intervention.
- Thus, women at high risk for breast cancer receiving the enhanced intervention exhibited an increase in their sense of preparedness in pursuing risk assessment/genetic testing services as well as an increase in their intention to pursue such services.
- Women at average risk in the enhanced intervention exhibited a decrease in intention to pursue genetic testing/risk assessment at 6-months compared to average risk women in the standard intervention.
- Women at average risk in the enhanced intervention exhibited a decrease in preparation to pursue genetic testing/risk assessment at 6-months compared to average risk women in the standard intervention.
- There were no significant differences, either main effects or interaction effects, at the 2-week, 2-month, and 6-month time-points in satisfaction with the CIS.
- Women at high risk for breast cancer indicated high levels of satisfaction with the enhanced intervention despite its length, suggesting the feasibility of implementing it as the standard of service within the CIS for this population.

- High monitors AT AVERAGE RISK had greater satisfaction with CIS when receiving the enhanced intervention as compared to standard care. Conversely, low monitors at average-risk displayed greater satisfaction when they received the standard care condition as compared to the enhanced intervention. This is the pattern of results typically obtained in the literature for high vs. low monitors.
- High monitors AT HIGH GENETIC RISK reported greater satisfaction when they received standard care than with the enhanced protocol, while low monitors at high-risk were more satisfied when receiving the enhanced intervention over standard care. This finding suggests that when the risk is more intense, voluminous information may be too threatening and not sufficiently reassuring for high monitors.

Reportable Outcomes

Manuscripts

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Abstracts & Presentations

2001 Annual Retreat for Cancer Research: April 25, 2001. Princeton, NJ

WOMEN'S SELF-REPORTED KNOWLEDGE ABOUT CANCER RISKS, RISK ASSESSMENT AND GENETIC TESTING: PRELIMINARY FINDINGS* - *Linda Fleisher, M.P.H., Nancy McKeown-Conn, M.BE. Atlantic Region CIS and Suzanne*

*Miller, Ph.D., Robert Schnoll, Ph.D., Lisa Brower, B.A., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

American Society of Preventive Oncology (ASPO): *25th Annual Meeting:* March 11-13, 2001. New York, New York.

WOMEN'S SELF-REPORTED KNOWLEDGE ABOUT CANCER RISKS, RISK ASSESSMENT AND GENETIC TESTING: PRELIMINARY FINDINGS* - *Linda Fleisher, M.P.H., Nancy McKeown-Conn, M.BE. Atlantic Region CIS and Suzanne Miller, Ph.D., Robert Schnoll, Ph.D., Lisa Brower, B.A., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Era of Hope: Department of Defense Breast Cancer Research Meeting: June 8-11, 2000. Atlanta, Georgia.

DEVELOPMENT OF AN INTERVENTION TO INCREASE WOMEN'S KNOWLEDGE OF CANCER RISK & RISK PROGRAMS - Linda Fleisher, M.P.H., Suzanne M. Miller, Ph.D., Robert Schnoll, Ph.D, Nancy McKeown-Conn, B.A., Lisa Brower, B.A, Fox Chase Cancer Center, Atlantic Region Cancer Information Service

Fox Chase Cancer Center: National Cancer Institute Core Grant Site Visit: Overview of Population Science Facilities, October, 2000.

DEMONSTRATION OF CATI SYSTEM* - Elyse Slater, Susan Raysor, Fox Chase Cancer Center *(*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Fox Chase Cancer Center: Information Technology Information Exchange Seminar, February 1, 2001.

CREATING A WEB-BASED, COMPUTER ASSISTED TELEPHONE INTERVIEW SYSTEM* - Elyse Slater, Susan Raysor, Fox Chase Cancer Center *(*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Pennsylvania Public Health Association (PPHA): *Public Health Challenges 2010.* Oct. 4-6, 2000. Harrisburg, PA

DEVELOPMENT OF AN INTERVENTION TO INCREASE WOMEN'S KNOWLEDGE OF CANCER RISK & RISK PROGRAMS* - *Nancy McKeown-Conn, M.Be., Fox Chase Cancer Center (*Supported by the US Army Medical Research & Materiel Command DAMD 17-98-1-8306)*

Funding applied for based on work supported by this grant.

- **American Cancer Society**, Pilot Study to Access the Feasibility of a Cognitive-Behavioral Smoking Cessation and Relapse Prevention Intervention for Pregnant, Low-income Minority Women

- **Department of Defense**, Behavioral Center of Excellence, Project 1, Understanding Breast Cancer Risk Assessment and Screening among the Underserved
- **Department of Defense**, Behavioral Center of Excellence, Communications Core
- **National Cancer Institute,** Pilot Projects To Overcome The Digital Divide (PRODD) – Communities Addressing the Digital Divide
- **National Cancer Institute,** R21, Communities Addressing the Digital Divide
- **National Cancer Institute,** Specialized Program of Research Excellence (**SPORE**) in Ovarian Cancer

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Nancy McKeown-Conn, M.Be.
Suzanne Miller, Ph.D.
Virginia Nunn, B.S.
Cherie Riggs, B.A.
Robert Schnoll, Ph.D.
Stephen Torres

Conclusions

Study data corroborate current literature suggesting that women lack knowledge about and are unprepared for the process of cancer risk assessment and genetic testing. In addition, the data supports the rationale and need for this study and others like it. The majority of women (56%) who agreed to participate in this pilot indicated that they would not feel adequately prepared to pursue risk assessment services. In addition, women were found to be lacking important information that would enable them to make informed decisions about pursuing risk assessment and genetic testing. When women were asked to rate their degree of knowledge concerning breast and ovarian cancer risks and the process of risk assessment and genetic testing, 61% of them indicated that they have inadequate knowledge. This self-reported lack of knowledge is substantiated by a large proportion of incorrect responses to questions about age as a risk factor, inheriting breast cancer gene mutations from one's father, and the links between breast and ovarian cancers, among others. Baseline data confirm the need for more and better information about breast/ovarian cancer risks, risk assessment and genetic testing.

This randomized study, in which the standard intervention was compared to the enhanced intervention, tested the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing as well as her sense of preparation and intention to pursue such services. Although genetic counseling professionals agree that any woman seeking risk assessment services benefits from the educational sessions, these programs are established primarily for those at increased risk for

cancer. So, we expected to see an increase in intention to pursue risk assessment/genetic counseling services among those women at high risk receiving the enhanced intervention. Conversely, we expected women at average risk receiving the enhanced intervention to demonstrate a decrease in intention. In fact, this is what we found. There was a significant increase in intention to pursue genetic testing/risk assessment after 6-months for women at high risk only in the enhanced intervention compared to high-risk women in the standard intervention. Women at average risk in the enhanced intervention exhibited a decrease in intention to pursue genetic testing/risk assessment at 6-months compared to average risk women in the standard intervention. Results also demonstrate a positive effect for high-risk women in the intervention group in increasing a sense of preparation in pursuing such services. Thus, women at high risk for breast cancer receiving the enhanced intervention exhibited an increase in their sense of preparedness in pursuing risk assessment/genetic testing services as well as an increase in their intention to pursue such services. The implications of these findings are important, given the effectiveness of chemoprevention and other risk reduction options for this high-risk population.

We hypothesized that women receiving the enhanced intervention would show a greater increase in knowledge than the standard group and that the high-risk group, who would be more invested in the information, would demonstrate the greatest increases. This hypothesis was not borne out by the data. In fact, knowledge increases were shown only in women at average risk and only at the first and second follow-up time points. The intervention had no effect on knowledge.

That the enhanced intervention was considerably lengthier than the standard raised concerns that satisfaction levels would be negatively affected. But, there were no differences in levels of satisfaction with the CIS, either main effects or interaction effects, at any of the follow-up time points. This finding is important as it reinforces the role of the CIS in educating all women about breast/ovarian cancer risks in a way that is satisfactory to them. Moreover, it strengthens the CIS' position as the foremost provider of tailored cancer information as the findings suggest that the enhanced intervention, proven effective at increasing participants' intention and preparedness in pursuing cancer risk assessment, may be feasible to adopt as the standard of service for women at high risk for cancer.

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Appendices
Appendix A

Project Advisory Committee Members (Attending)

Marilyn Arnott, Ph.D.	*Living Beyond Breast Cancer*
Carol Blickley	*Family Risk Assessment Program*
Barbara DeLuca	*Linda Creed Breast Cancer Foundation*
Paul Engstrom, M.D.	*Fox Chase Cancer Center*
Caryn Lerman, Ph.D.	*Georgetown University*
Novella Lyons	*Women of Faith and Hope*
Agnes Masny, R.N., M.P.H., M.S.N.	*Fox Chase Cancer Center*
Judi Much, R.N., M.S.N.	*Cancer Institute of New Jersey*
Joan Pouch	*Family Risk Assessment Program*
Linda Slan, M.S.	*Cancer Information Service Branch/NCI*
Laura Toole, M.S.	*Northeast Regional Cancer Center*

Project Advisory Committee Members (Unable to Attend)

Generosa Grana, M.D.	*Cooper Medical Center*
Pamela Sankar, Ph.D.	*Center for Bioethics, U. of P.*
Jill Stopfer, M.S.	*University of Pennsylvania*

Project Staff

Suzanne M. Miller, Ph.D.	*Director, Psychosocial and Behavioral Medicine*
Linda Fleisher, M.P.H.	*Project Director, Cancer Information Service*
Robert Schnoll, Ph.D.	*Research Associate*
Lisa Brower, B.A.	*Research Assistant*
Kim Le Maitre, B.S.	*Training Coordinator, CIS*
Nancy McKeown-Conn, B.A.	*Research Coordinator, CIS*
Cherie Riggs, M.A.	*Assistant Project Director, CIS*

Appendix B
ECRF # _____

Staff ID _____

Date _____

STANDARD INTERVENTION

Start Time _____
(Follows informed consent document)

Caller is asking about: ☐ Breast Cancer ☐ Ovarian Cancer ☐ Both

Let me begin by asking just a few short questions:

1) Have you ever been diagnosed with cancer? ☐ YES ☐ NO ☐ Don't Know ☐ Refused

If yes - What kind of cancer were you diagnosed with? Age (at diagnosis)?

If no, continue with question 2.

2) Have you ever pursued risk assessment services? ☐ YES ☐ NO

If yes – When?

If no, continue with question 3.

Please read all responses for the following questions. (Questions read verbatim)

3) At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment and genetic testing for breast and ovarian cancer? (Please circle)

1. Very knowledgeable
2. Somewhat knowledgeable
3. Not very knowledgeable
4. Not at all knowledgeable

4) If you chose to pursue risk assessment and genetic testing, how prepared would you feel?

1. Not at all prepared
2. Somewhat prepared
3. Quite prepared
4. Very prepared
5. Don't know
6. Refused

5) I am going to read a few statements. Please tell me which one best describes you.

1. I participated in a risk assessment and counseling program in the past 6 months.
2. I am planning to contact a risk assessment and genetic counseling program in the next 30 days.
3. I am planning to contact a risk assessment and genetic counseling program in the next 6 months.
4. I am thinking about contacting a risk assessment and genetic counseling program, but I'm not really sure and have made no specific plan.
5. I am not thinking about contacting a risk assessment and genetic counseling program.

Cancer Risk Concerns Survey

You called today because you have some concerns about your risk of developing **(refer to cancer site)** *breast/ovarian cancer. What things do you think contribute to your risk for breast/ovarian cancer?* **(Place an 'x' in the box(es) next to caller's response(s))**

Known Risks

- ☐ Age
- ☐ Early Menarche
- ☐ Late Menopause
- ☐ Family History/Genetics (BRCA 1 & 2)
- ☐ Personal History of Cancer
- ☐ Pregnancy/children
- ☐ Previous Breast Biopsies (particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)

Possible Risks

- ☐ Lifestyle
  - ☐ Diet
  - ☐ Smoking
  - ☐ Exercise
  - ☐ Alcohol
  - ☐ Stress
- ☐ Personal Health History
  - ☐ HRT
  - ☐ DES
  - ☐ Abortion
  - ☐ Oral Contraceptives
- ☐ Environment
- ☐ Other (please specify)_____

(Use this sheet to review general risks after the baseline knowledge and perception survey)

Those are (That is an) important factor(s) for us to discuss and I can provide you with information about your concern(s). First, I'd like to ask you some questions about what you have heard about risk factors for breast and ovarian cancer and then we will come back and discuss your concerns in depth.

Knowledge and Perception Survey

Please read all responses to caller. (Questions and statements read verbatim)

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

don't know	refused

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3

A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

4) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

5) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) *Breast and Ovarian Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.*

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment and genetic testing is that finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment and genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Review of General Risks

Information Specialist will refer to the Cancer Risks Concerns Survey (p. 2) to review general risks using NCI materials.

Thank you for answering those questions. Now let's go back to your concerns about cancer risks. You mentioned that .....is/are risk factors. And you're correct. But some other things you should know about include...(**Mention proven risk factors NOT mentioned by caller as well as HRT and OC, then clarify any misconceptions the caller might have) Use WYNTK Breast as reference.**

****Place a check mark in all risk factors you addressed that the caller did not mention****

Known Risks (Specialist must mention all of these)

- ☐ Age*
- ☐ Early Menarche (before age 12)*
- ☐ Late Menopause (after age 55)*
- ☐ Family History/Genetics (BRCA 1 & 2)*
- ☐ Personal History of Cancer*
- ☐ Pregnancy/children (having first child after age 30 or having no children)*
- ☐ Previous Breast Biopsies *(*particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)*

Possible Risks (Specialist MUST mention HRT & OC in addition to addressing any concerns mentioned in this section by the caller – e.g., *there is some suggestion that alcohol may increase a woman's chance of getting breast cancer*)

Scientists are exploring other possible risks for breast cancer. For example, they're trying to determine whether taking birth control pills or hormone replacement therapy for post-menopausal symptoms increases a woman's risk of getting breast cancer. They hope to find the answer by studying a large number of women taking part in hormone related research. If you have questions about these and other possible risks, it might be helpful to discuss them with your doctor or other health care provider.

- ☐ HRT*
- ☐ Oral Contraceptives*

Comments | **Comments**

Are there any questions or concerns you have about these risk factors?

Review of Sporadic, Familial and Inherited Cancer Patterns

Now I'd like to give you some information about the different ways cancer can occur. There are three patterns of cancer: sporadic, familial and hereditary. **(Read descriptions verbatim)**

Sporadic - ***Most breast cancers, about 70% are sporadic. That means that these cancers happen by chance as a result of changes in a woman's body that occur during her lifetime.***

Familial - ***In about 20% of breast cancer cases, there is already a pattern of breast cancer in a woman's family. These cancer patterns are called familial. The other members of these families have an increased risk of breast cancer. The risk of breast cancer may be higher in these families because of similar environments that family members share or because of an inherited susceptibility.***

Hereditary - ***There are cancer patterns in which the family history is so strong that it appears members of the family may be inheriting a certain gene, or combination of genes, that puts them at greater risk for cancer. These cancer patterns are called hereditary.***
About 10% of all breast cancers fall into the hereditary cancer pattern.

(Information Specialist will check caller's understanding)

Today we've discussed risk factors for breast and ovarian cancer as well as the different types of cancer patterns. As I said in the beginning of the call, I can send you all this information. The materials I'll be sending will address everything we've talked about today. They will also go into greater detail on some of the things I've only mentioned briefly. Do you have any questions about what we've discussed today?

Would you be interested in a referral to a risk counseling/genetic testing program?

(1) ☐ YES (2) ☐ NO

If YES: Give regional referral. Please note which referrals were given.

1. _____
2. _____
3. _____
4. _____
5. _____

By the way, the packet of information will include a list of risk assessment and genetic testing facilities in the Pennsylvania, New Jersey, and Delaware region.

Before we conclude this call we have just a few last questions we would like to ask you. The next couple of questions are regarding your current preventive practices. Once again please be assured that all information provided is kept confidential.

(Questions read verbatim)

1. *How often do you perform Breast Self Exam (BSE)?*

(10) ☐ more than once a week
(20) ☐ at least once a week
(30) ☐ a couple of times a month
(40) ☐ at least once a month
(50) ☐ a few times each year
(60) ☐ at least once a year
(70) ☐ almost never
(80) ☐ never
(97) ☐ don't know
(98) ☐ refused

2. *How often do you go for mammograms?*

(1) ☐ once every few months
(2) ☐ a couple of times each year
(3) ☐ once a year
(4) ☐ once every few years
(5) ☐ almost never
(6) ☐ never
(7) ☐ don't know
(8) ☐ refused

3. **(For ovarian cancer callers only)** In *the past six months:*

How many transvaginal ultrasounds have you had? _____ (98) ☐ Refused ☐ N/A
How many pelvic exams have you had? _____ (98) ☐ Refused ☐ N/A
How many CA 125 blood tests have you had? _____ (98) ☐ Refused ☐ N/A

Information specialist will read all responses to the caller.

4. *Which of the following categories bests describes you? Are you:*

(10) ☐ Asian or Pacific Islander
(20) ☐ African American/Black
(30) ☐ Hispanic
(40) ☐ American Indian/Alaskan Native
(50) ☐ White
(60) ☐ Other
(98) ☐ Refused

2. *May we ask what is the highest level of education you have achieved?*

(1) ☐ Grade School
(2) ☐ Some High School
(3) ☐ High School Graduate
(4) ☐ Some College
(5) ☐ College Graduate
(6) ☐ Post-Graduate
(8) ☐ Refused

Information specialist will read all responses to the caller.

6. *How satisfied do you feel with the information you received today?*

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

don't know	refused
7	8

7. *To what extent would you recommend that others contact the Cancer Information Service for this information?*

definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

don't know	refused
7	

End Time _____

Complete ECRF. Remember to enter ECRF number on both forms: the intervention and the informed consent.

Thank you for calling the Cancer Information Service. I will send the information we've discussed. Is there anything else I can help you with today?

Appendix C
ECRF # _____

Staff ID _____

Date _____

ENHANCED INTERVENTION

Start Time _____

(Follows informed consent document)

Caller is asking about: ☐ Breast Cancer ☐ Ovarian Cancer ☐ Both

Let me begin by asking just a few short questions:

1) Have you ever been diagnosed with cancer? ☐ YES ☐ NO ☐ Don't Know ☐ Refused

If yes - What kind of cancer were you diagnosed with? Age (at diagnosis)?

If no, continue with question 2.

3) Have you ever pursued risk assessment services? ☐ YES ☐ NO

If yes – When?

If no, continue with question 3.

Please read all responses for the following questions. (Questions read verbatim)

3) At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment and genetic testing for breast and ovarian cancer? (Please circle)

5. Very knowledgeable
6. Somewhat knowledgeable
7. Not very knowledgeable
8. Not at all knowledgeable

4) If you chose to pursue risk assessment and genetic testing, how prepared would you feel?

7. Not at all prepared
8. Somewhat prepared
9. Quite prepared
10. Very prepared
11. Don't know
12. Refused

5) I am going to read a few statements. Please tell me which one best describes you.

1. I participated in a risk assessment and counseling program in the past 6 months.
2. I am planning to contact a risk assessment and genetic counseling program in the next 30 days.
3. I am planning to contact a risk assessment and genetic counseling program in the next 6 months.
4. I am thinking about contacting a risk assessment and genetic counseling program, but I'm not really sure and have made no specific plan.
5. I am not thinking about contacting a risk assessment and genetic counseling program.

Cancer Risk Concerns Survey

You called today because you have some concerns about your risk of developing **(refer to cancer site)** *breast/ovarian cancer. What things do you think contribute to your risk for breast/ovarian cancer?* **(Place an 'x' in the box(es) next to caller's response(s))**

Known Risks

- ☐ Age
- ☐ Early Menarche
- ☐ Late Menopause
- ☐ Family History/Genetics (BRCA 1 & 2)
- ☐ Personal History of Cancer
- ☐ Pregnancy/children
- ☐ Previous Breast Biopsies (particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)

Possible Risks

- ☐ Lifestyle
  - ☐ Diet
  - ☐ Smoking
  - ☐ Exercise
  - ☐ Alcohol
  - ☐ Stress
- ☐ Personal Health History
  - ☐ HRT
  - ☐ DES
  - ☐ Abortion
  - ☐ Oral Contraceptives
- ☐ Environment
- ☐ Other (please specify)_____

(Use this sheet to review general risks after the baseline knowledge and perception survey)
Those are (That is an) important factor(s) for us to discuss and I can provide you with information about your concern(s). First, I'd like to ask you some questions about what

you have heard about risk factors for breast and ovarian cancer and then we will come back and discuss your concerns in depth.

Knowledge and Perception Survey

Please read all responses to caller. (Questions and statements read verbatim)

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

8 don't know 8 refused

c.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

8 don't know 8 refused

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

8 don't know 8 refused

c.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

don't know refused

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2

Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

7) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) *Breast and Ovarian Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.*

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment and genetic testing is that finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment and genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Review of General Risks

Information Specialist will refer to the Cancer Risks Concerns Survey (p. 2) to review general risks using NCI materials.

Thank you for answering those questions. Now let's go back to your concerns about cancer risks. You mentioned that .....is/are risk factors. And you're correct. But some other things you should know about include...(**Mention proven risk factors NOT mentioned by caller as well as HRT and OC, then clarify any misconceptions the caller might have) Use WYNTK Breast as reference.**

****Place a check mark in all risk factors you addressed that the caller did not mention****

Known Risks (Specialist must mention all of these)

- ☐ Age*
- ☐ Early Menarche (before age 12)*
- ☐ Late Menopause (after age 55)*
- ☐ Family History/Genetics (BRCA 1 & 2)*
- ☐ Personal History of Cancer*
- ☐ Pregnancy/children (having first child after age 30 or having no children)*
- ☐ Previous Breast Biopsies **(particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)*

Possible Risks (Specialist MUST mention HRT & OC in addition to addressing any concerns mentioned in this section by the caller – e.g., *there is some suggestion that alcohol may increase a woman's chance of getting breast cancer*)

Scientists are exploring other possible risks for breast cancer. For example, they're trying to determine whether taking birth control pills or hormone replacement therapy for post-menopausal symptoms increases a woman's risk of getting breast cancer. They hope to find the answer by studying a large number of women taking part in hormone related research. If you have questions about these and other possible risks, it might be helpful to discuss them with your doctor or other health care provider.

- ☐ HRT*
- ☐ Oral Contraceptives*

Comments | **Comments**

Are there any questions or concerns you have about these risk factors?

Review of Basic Genetics and Cancer (Verbatim)

There are a few facts you should know about the role of genes in the development of cancer, particularly in the development of breast and ovarian cancers

- *You get half your genes from your mother and the other half from your father.*
- *People with hereditary breast and ovarian cancer have inherited a changed or mutated gene from one of their parents. But they still have one normal copy of the gene from the other parent.*
- *Something needs to occur to the normal gene before a cancer will develop. That explains why not all people with cancer gene mutations get cancer – nothing ever happened to alter the normal gene.*
- *Scientists are beginning to identify which of our genes are related to cancer. So far, they have identified two genes which, when altered, can cause breast and ovarian cancer. One gene is known as BRCA 1. It appears to cause cancers in the breast and ovaries. Another gene, BRCA 2, was also identified. It appears to cause mainly breast cancer, but it may also cause ovarian and prostate cancers. BRCA 2 is believed to be responsible for some cases of breast cancer in men.*

Review of Sporadic, Familial and Inherited Cancer Patterns

Now I'd like to give you some information about the different ways cancer can occur. There are three patterns of cancer: sporadic, familial and hereditary. **(Read descriptions verbatim)**

Sporadic - ***Most breast cancers, about 70% are sporadic. That means that these cancers happen by chance as a result of changes in a woman's body that occur during her lifetime.***

Familial - ***In about 20% of breast cancer cases, there is already a pattern of breast cancer in a woman's family. These cancer patterns are called familial. The other members of these families have an increased risk of breast cancer. The risk of breast cancer may be higher in these families because of similar environments that family members share or because of an inherited susceptibility.***

Hereditary - ***There are cancer patterns in which the family history is so strong that it appears members of the family may be inheriting a certain gene, or combination of genes, that puts them at greater risk for cancer. These cancer patterns are called hereditary. About 10% of all breast cancers fall into the hereditary cancer pattern.***

(Information Specialist will check caller's understanding)

Review of Hallmarks of Inherited Breast/Ovarian Cancer

There are several characteristics or signs that help determine if a cancer fits a hereditary pattern. These are:

1. ***The number of relatives with breast cancer.*** The more relatives there are in the family with breast cancer, the more likely it is to be a hereditary pattern. Also, both your mother and father's sides of the family are important since the altered gene can be passed down through either side.
2. ***Occurrence in every generation.*** In the hereditary cancer pattern, there is usually someone in each generation who develops the disease. So, if a woman's sister, mother and maternal grandmother (mother's mother) all had breast cancer, it is most likely a hereditary pattern. There are some exceptions. For example, the *altered* gene is just as likely to be passed on to a son as to a daughter. Since males don't usually get breast cancer, it can skip his generation, making the pattern harder to see. He can, however, pass the gene on to his children.
3. ***Occurrence of other cancers in the family.*** There are a few other types of cancer associated with the hereditary pattern of breast cancer. They are ovarian cancer in women and prostate cancer in men.
4. ***The age when the cancer occurs.*** Most breast cancers occur in women aged 50 or older. In fact, a woman's chance of getting breast cancer increases with age. One in eight women will develop breast cancer in her lifetime and most of those cancers will be sporadic, or caused by chance. When there is a hereditary pattern, the cancer sometimes occurs at younger ages, in the 30's or 40's. The same may be true for ovarian cancer if it is part of a hereditary pattern.
5. ***Breast cancers that occur in both breasts.*** This is called *bilateral* breast cancer. The woman who gets cancer in both breasts instead of just one tend to fit into the hereditary cancer pattern.
6. ***Jewish Ancestry.*** While it is not known whether breast cancer is more prevalent in women of Ashkenazi (Eastern European) Jewish descent than in the general population, researchers recently identified specific gene alterations which are particularly prevalent in this population.

(Information Specialist will check caller's understanding)

Family Cancer History

We've talked about family history as a risk factor for breast and ovarian cancers. We've also discussed different cancer patterns and some of the signs or characteristics that could indicate an inherited cancer. One of the first steps a person would need to take to find out more about her personal risk for hereditary cancer would be to obtain as complete a family cancer history as possible. I am not a genetic counselor or a doctor and I certainly cannot interpret your risk over the phone. But what I'd like to do is to ask some questions about your family history that I'll send to you. You might want to take this information to your health care provider so the two of you can discuss any concerns you might have about your risk and whether or not risk assessment services would be appropriate for you. I'd like to begin by asking you some questions about your family history that include their relationship to you, their age when they were diagnosed, their current age (if they're still alive) and the kind of cancer they had.

(If caller has a history of cancer, begin with her and recap the information given previously. Otherwise, begin with the immediate family. E.g., *Has anyone in your immediate family ever been diagnosed with cancer? How about your mother? Anyone else – father, siblings, children? Did anyone on your mother's side ever have cancer? Etc.*)
Probe Immediate family, mother's side, father's side.

	Breast Cancer Age at diagnosis:	Ovarian Cancer Age at diagnosis:	Colon Cancer Age at diagnosis:	Other (Specify) Age at diagnosis:	Unknown	No Cancer
Mother Current Age						
Father Current Age						
Sister(s) Current Age						
Brother(s) Current Age						
Children Current Age						

Mother's Side

	Breast Age at dx	Ovarian Age at dx	Colon Age at dx	Other Age at dx	Unknown	No Cancer
Grandmother Age:						
Grandfather Age:						
Aunt(s) Age:						
Uncle(s) Age:						
Cousin(s) Age						

Father's Side

	Breast Age at dx	Ovarian Age at dx	Colon Age at dx	Other Age at dx	Unknown	No Cancer
Grandmother Age:						
Grandfather Age:						
Aunt(s) Age:						
Uncle(s) Age:						
Cousin(s) Age:						

Challenges in Interpreting Family History Information

(Read verbatim)

You should be aware that there are many challenges in interpreting family history information and sometimes it can be very difficult to make a determination about whether the cancer in the family appears to be sporadic, familial or hereditary. For example, if the family was very small or if information on several people is missing, it would be hard to find a hereditary pattern even if one exists. For these reasons, it is important to talk to your doctor, or a professional trained in genetics, such as a genetic counselor.

(Information Specialist will summarize and check caller's understanding)

Process and Services (*new field*)

Let's talk now about what happens when a woman goes for risk assessment, high risk counseling and/or genetic testing? What have you heard is involved in such programs?
(Please place an 'x' next to all that apply)

Caller	**IS**	
(10)☐	☐	Counseling
(20)☐	☐	Family history (pedigree)
(30)☐	☐	Information/Education (group and/or individual sessions)
(40)☐	☐	Blood work for BRCA 1/2 (Perhaps. * Testing is not done without counseling. Results are never back the same day. *)
(50)☐	☐	Medical records (perhaps)
(60)☐	☐	A process (often takes place over a period of time)
(70)☐	☐	Screening (mammography, CA125, BSE, etc)
(80)☐	☐	Multidisciplinary Team (they'll be seen by more than one health professional)
(90)☐	☐	Other (please write in) _____

Many of the things you've mentioned are involved in risk assessment and genetic testing. Other things you should know about participating in any risk assessment program include:

Mention anything not checked and place a check mark in the corresponding box.

Clarify misconceptions using NCI materials

Comments

Note all of the following:

- ☐ *Programs vary from institution to institution*
- ☐ *It is important to know why risk assessment and genetic testing are important to you as well as how the information will change your behavior.*
- ☐ *Cost may be expensive if not done as part of research*
- ☐ *You might not get test results if you are part of a research study*
- ☐ *Insurance might not cover the risk assessment/counseling services or the testing*

☐ *It might take some time to get an appointment (That's OK)*

☐ *Should you decide to get tested, results may not be available for some time (up to 2 years)*

Pros and Cons of Risk Assessment/Genetic Testing (*new field*)

From your perspective, what are the advantages of risk assessment and genetic testing? **(Please place an 'x' next to all that apply)**

(10)**Risk Assessment**

Caller	*IS*	
(11)☐	☐	Gain information about personal familial risk
(12)☐	☐	Increase understanding of risk factors for cancer
(13)☐	☐	Help in deciding whether or not to undergo genetic testing

(20)**Risk Assessment/Genetic Testing**

(21)☐	☐	Acquire information that can help make lifestyle changes (e.g., nutrition,
(22)☐	☐	Make plans to increase or change surveillance and/or screening (e.g., more frequent mammograms, BSE) – *Currently, the National Cancer Institute recommends regular mammograms for women over age 40 (every 1-2 years). Women at increased risk might require more frequent mammograms.*
(23)☐	☐	Information for the entire family
(24)☐	☐	Contributes to research
(25)☐	☐	Help make child-bearing decisions
(26)☐	☐	Relieve self and family of worry and anxiety about risk

(30)**Genetic Testing**

(31)☐	☐	Confirm whether or not gene -/+
(32)☐	☐	Help decide whether or not to pursue preventive treatments (e.g., mastectomy, oophorectomy, tamoxifen)
(33)☐	☐	Other (please write in) _____

Yes. Some other advantages include: **(mention those not checked)**

From your perspective, what do you think are the disadvantages of risk assessment and genetic testing?(new field) **(Please check all that apply and place a check mark in the corresponding box)**

(10)☐	☐	Insurance (Health and/or Life) – inability to obtain or loss of
(11)☐	☐	Employment discrimination

(12)☐	☐	Confidentiality
(13)☐	☐	No guaranteed way to prevent cancer
(14)☐	☐	Survivor's guilt
(15)☐	☐	Cost
(16)☐	☐	Guilt re: the possibility of passing on a + gene to one's children
(17)☐	☐	Might have a negative impact on the family
(18)☐	☐	May be harder to cope with cancer risk if you know the test results
(19)☐	☐	Negative test results may lead to a false sense of security
(20)☐	☐	Test results may be indeterminate
(21)☐	☐	Tests may not be able to precisely determine risk
(22)☐	☐	Don't trust modern medicine
(90)☐	☐	Other (please write in) _____

Yes. Some other disadvantages include: **(mention those not checked and place a check mark in the corresponding box.)**

Comments

(Information Specialist will check caller's understanding)

We've discussed many things today - cancer risks, the different kinds of cancer patterns, basic cancer genetics as well as what's involved in risk assessment, risk counseling and genetic testing. As I said in the beginning of the call, I can send you all this information. The materials I'll be sending will address everything we've talked about today. They will also go into greater detail on some of the things I've only mentioned briefly. Do you have any questions about what we've discussed today?
Would you be interested in a referral to a risk counseling/genetic testing program?

(1) ☐ YES (2) ☐ NO

If YES: Give regional referral. Please note which referrals were given.

1. _____
2. _____
6. _____
7. _____
8. _____

By the way, the packet of information will include a list of risk assessment and genetic testing facilities in the Pennsylvania, New Jersey, and Delaware region.

Before we conclude this call we have just a few last questions we would like to ask you. The next couple of questions are regarding your current preventive practices. Once again please be assured that all information provided is kept confidential.

(Questions read verbatim)

2. *How often do you perform Breast Self Exam (BSE)?*

(10) ☐ more than once a week
(20) ☐ at least once a week
(30) ☐ a couple of times a month
(40) ☐ at least once a month
(50) ☐ a few times each year
(60) ☐ at least once a year
(70) ☐ almost never
(80) ☐ never
(97) ☐ don't know
(98) ☐ refused

2. *How often do you go for mammograms?*

(1) ☐ once every few months
(2) ☐ a couple of times each year
(3) ☐ once a year
(4) ☐ once every few years
(5) ☐ almost never
(6) ☐ never
(7) ☐ don't know
(8) ☐ refused

3. **(For ovarian cancer callers only)** In *the past six months:*

How many transvaginal ultrasounds have you had? _____ (98) ☐ Refused ☐ N/A

How many pelvic exams have you had? _____ (98) ☐ Refused ☐ N/A

How many CA 125 blood tests have you had? _____ (98) ☐ Refused ☐ N/A

Information specialist will read all responses to the caller.

4. *Which of the following categories bests describes you? Are you:*

(10) ☐ Asian or Pacific Islander
(20) ☐ African American/Black
(30) ☐ Hispanic
(40) ☐ American Indian/Alaskan Native
(50) ☐ White
(60) ☐ Other
(98) ☐ Refused

3. *May we ask what is the highest level of education you have achieved?*

(1) ☐ Grade School
(2) ☐ Some High School
(3) ☐ High School Graduate
(4) ☐ Some College
(5) ☐ College Graduate
(6) ☐ Post-Graduate
(8) ☐ Refused

Information specialist will read all responses to the caller.

6. *How satisfied do you feel with the information you received today?*

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

don't know	refused
7	8

7. *To what extent would you recommend that others contact the Cancer Information Service for this information?*

definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

don't know	refused
7	

End Time _____

Complete ECRF. Remember to enter ECRF number on both forms: the intervention and the informed consent.

Thank you for calling the Cancer Information Service. I will send the information we've discussed. Is there anything else I can help you with today?

Appendix D

DOD GRANT
Training Curriculum

Introduction
< Background on the DOD Grant
< Training
  < Purpose
  < Schedule

Session 1: Basic Concepts in Genetics
< DNA Basics
  < Genes & Chromosomes
< Mutations
  < Patterns of inheritance
< Overview of Carcinogenesis
  < Cell Cycle
  < Cell Death

Session 2: Patterns of Cancer & Assessing Risk
< Sporadic, familial and hereditary patterns of cancer
< Pedigrees
  < the importance of the family history information

Session 3: The Role of Genes in Cancer
< Identify genes responsible for breast and ovarian cancer
  < BRCA1
  < BRCA2

Session 4: Inherited Risk
< Definition
< Factors that influence risk perception
< Current risk models
  < Estimating risk
< Presenting risk information
  < Impact of cancer risk information

Session 5: Genetic Counseling & Services
< The role of the genetic counselor
< The range of programs and services

Session 6: Genetic Testing

< Considerations
  < Who should be tested
  < Reason for testing
    < Patient perspective
    < Physician perspective
  < How will test result influence medical management
< Informed consent
< Techniques used
< Interpreting results
  < What does it all mean for the patient
< Benefits
< Risks
< Limitations
< Ethical, Legal and social issues
< Psychological issues
  < Ethnic and cultural issues
< Management strategies and follow-up

Session 7: Putting it all together

< Case studies
< Group discussions

Session 8: Intervention, Study Procedures & Resources

< Overview of Study
  < Importance of the CIS in research
< Informed consent
< Interventions
< Resources
  < Content and referral resources
< Mailouts
< Follow-up
< Issues

Appendix E

DOD SURVEY QUESTIONS

Please circle the correct answers.

1. A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer. T F

2. Breast cancer that occurs at a younger age (before 50) is less likely due to an altered BRCA1 gene than breast cancer that occurs after age 50. T F

3. A sister of a woman with an altered BRCA1 or BRCA2 gene has a 50% chance of having the altered gene. T F

4. If no alteration on BRCA1 or BRCA2 is found in a family with a lot of breast cancer, there could still be another breast cancer gene alteration at work. T F

5. A father can pass down an altered BRCA1 or BRCA2 gene to his children. T F

6. All women who have an altered BRCA1 or BRCA2 gene will get breast cancer. T F

7. DNA is located:
   A. In the chromosomes.
   B. In the nucleus of the cell.
   C. In the enzymes that repair genetic errors.
   D. None of the above.

8. DNA makes proteins, and proteins make:
   A. Enzymes
   B. Amino acids
   C. Cells
   D. Genes

9. What is the goal of genetic testing? Circle all that apply.
   A. To identify those women who will eventually develop Breast cancer.
   B. To assure that individuals who test positive for a gene

alteration get appropriate medical follow-up.
C. To look for possible predisposition to disease as well as to confirm a suspected mutation in either an individual or family.
D. To provide individuals or families with important health information.
E. All of the above.

10. All of the following are risk factors for Breast cancer *except*:
A. Age
B. Family history
C. Personal history of breast cancer
D. Use of oral contraceptives

11. A pedigree is:
A. A device used to determine a person=s susceptibility to a specific disease.
B. A tool used by geneticists to look at a pattern of disease in a family.
C. A term used to describe the line of descendants of a pure-breed animal.
D. An instrument that measures an individuals risk of developing a cancer.

12. All of the following are benefits to genetic testing *except*:
A. To make better informed decisions concerning the future.
B. To help other family members.
C. To gain a sense of control or peace of mind.
D. To lead the way for all individuals to receive genetic testing.

13. Which of the following are characteristics of the BRCA1 gene? Circle all that apply.
A. Is located on Chromosome 17
B. Contains over 200 alterations
C. Lifetime risk for Breast cancer is 60 - 80%
D. Is a tumor suppressor gene

14. What is the difference between familial and hereditary patterns of breast cancer?
    A. There are less familial cancer cases than hereditary cancer cases.
    B. The family history is stronger in hereditary cancers than in familial cancers and may indicate a greater likelihood of having an altered BRCA1 or BRCA2 gene.
    C. Familial cases tend to occur in younger women whereas hereditary cases occur more frequently in older women.
    D. The more relatives there are in the family with breast cancer, the more likely it is that a familial pattern exists.

15. If one identical twin develops breast cancer, will the other twin develop breast cancer as well?
    A. Yes, the other twin will almost certainly develop breast cancer.
    B. No, both women will not have received the altered gene.
    C. The answer depends on the rest of the family history.
    D. The other twin has a higher risk for both breast and ovarian cancer.

16. How often do you find yourself referring women with a family history of breast cancer to a genetic counselor.
    frequently fairly often occasionally seldom never

17. How confident are you that the callers you refer for genetic counseling and testing are truly candidates for these services.
    very confident somewhat confident not very confident

18. Which of the following best describes how you feel about explaining the relationship between genes and cancer to a caller.
    very capable somewhat capable not at all capable

19. What is your current level of skill in providing information about the issues related to genetic testing.

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I=ve never done this task

20. How well can you explain the rationale for genetic testing to a caller.

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I=ve never done this task

21. What is your current level of skill in explaining the meaning of lifetime risk of developing a cancer to a caller.

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I=ve never done this task

22. How important do you think it is to obtain family history information from an individual considering genetic testing?
very important somewhat important not at all important

THANK YOU FOR YOUR RESPONSES!

Appendix F

DOD COURSE EVALUATION QUESTIONS

Course Contents
Please check or circle the correct answer.

	True	False
1. The BRCA1 mutation is an example of a germline mutation.		
2. The term penetrance refers to the likelihood that the presence of a mutated gene will actually result in disease.		
3. Autosomal recessive disorders develop in persons who inherit one copy of the mutant gene, from either parent.		
4. In familial cancer patterns, more than one type of cancer is present in the family and several family members are usually affected.		
5. Relative risk refers to the rate of new breast cancer cases during a given period of time, in a given population.		
6. At least a three-generation pedigree should be obtained when taking a cancer family history.		
7. The Gail risk model will overestimate risk in women with an extensive family history.		
8. Three distinct mutations on the BRCA1 gene have been identified in women of Ashkenazi Jewish descent.		
9. A woman with a true negative test result has the same risk of developing breast or ovarian cancer as other women in the general population.		
10. Life insurance companies may not use knowledge of a genetic predisposition to cancer in underwriting decisions.		

11. The Gail model calculates risk on all of the following factors except:
    A. The woman=s current age.
    B. The woman=s age at first menarche.
    C. The number of 1st and 2nd degree relatives.
    D. The number of breast biopsies.
    E. The woman=s age at 1st live birth.

12. All of the following are hallmarks of inherited breast cancer except:
    A. Breast and ovarian cancer in the same woman.
    B. Early onset of breast or ovarian cancer.
    C. Multiple cases of breast cancer.
    D. Early death of affected members from cancer.
    E. Occurrences of other cancers in the family.

13. Which of the following most influences an individual=s perception of risk?
    A. Perceptions about the disease
    B. Educational level.
    C. Personal and family experience.
    D. Cultural, social, and religious factors
    E. Personality traits.

14. Which of the following risk models calculates for the presence of a BRCA mutation?
    A. The Gail model.
    B. The Claus model.
    C. Both the Gail & Claus model.
    D. None of the above.

15. Genetic testing results may be expressed as:
    A. Positive, negative, indeterminate, inconclusive
    B. Positive, negative, unknown, inconclusive
    C. Positive, negative, undetermined, inconclusive
    D. Positive, negative, indeterminate, nonspecific

16. All of the following are limitations of genetic testing except:
    A. Finding an alteration can indicate increased risk of developing cancer, but it can not indicate if or when cancer will develop.
    B. If you are a carrier, there is much uncertainty about recommended preventative steps and their value.
    C. If an inherited gene is to blame, it is always either the BRCA1 or BRCA2 genes.
    D. In some families, multiple cases of cancer may reflect shared environmental exposures rather than genetic susceptibility.

17. If a woman tests positive for a BRCA1 or BRCA2 mutation, her children have a ___% chance of having inherited this mutation.
    A. 30%
    B. 50%
    C. 75%
    D. 90%

18. Which of the following are considered ethical and/or legal concerns related to genetic testing for cancer susceptibility?
    A. Informed consent
    B. Privacy and confidentiality
    C. Discrimination issues
    D. All of the above

19. The Health Insurance Portability & Accountability Act ensures all of the following except:
    A. Americans have access to group insurance when they change jobs.
    B. Medical information from genetic tests cannot be used to deny coverage to individuals seeking new health insurance.
    C. Life insurance companies cannot deny coverage based on the results of genetic tests.
    D. Prohibits health plans from charging higher premiums to an individual than to others in the group.

In the following questions, you are asked to make inferences from the information provided. Read the following case study and develop a matching pedigree in the space below.

BH, a 38 year old single woman of Italian, Jewish ancestry, is seeking a referral for genetic testing because of a family history of breast cancer:

- Her mother was diagnosed with breast cancer at age 48 and died at age 55.
- Her mother had 4 siblings;
  - a sister who was diagnosed with breast cancer at age 56 and died at age 63;
  - another sister who died from an unknown condition at an unknown age;
  - a sister who was diagnosed with ovarian cancer at age 51 and is still alive at age 58;
  - and a brother who is alive and well at age 61.
- BH=s maternal grandmother was diagnosed with breast cancer at age 62 and died 2 years later.
- BH has 2 other siblings, a brother and a sister. Her older sister was diagnosed at age 40 with breast cancer and developed ovarian cancer three years later. She is still alive at age 44. Her brother is alive and well at age 36.

20. Based on BH=s pedigree, what cancer pattern does her family most represent?
    A. Familial
    B. Hereditary
    C. Sporadic
    D. Unable to determine

21. When considering genetic testing, who else in BH=s family should be tested?
    A. Her aunt and uncle
    B. Her aunt only
    C. Her aunt and/or sister
    D. Her sister only

II. Training Assessment

Using a scale from 1 (Not at all) to 5 (Very much), please indicate your response to the following questions:

	Not at all		**Somewhat**		**Very Much**
This training has improved my understanding of genetics.	1	2	3	4	5
I feel more confident in discussing the issues related to inherited breast and ovarian cancer to callers.	1	2	3	4	5

This training has strengthened my knowledge of the genetic counseling process.	1	2	3	4	5
I can explain the relationship between gene mutations and cancer to callers with greater confidence.	1	2	3	4	5
This training has improved my skill level in explaining the issues related to genetic testing.	1	2	3	4	5

III. Follow-up

Name three skills that you have gained or strengthened as a result of the training?

_____

_____

_____

What three things are you going to do to further develop your skills surrounding genetics, inherited risk, and genetic testing?

_____

_____

_____

What one thing are you going to do differently on your calls as a result of this training?

_____

_____

THANK YOU

Appendix G

Informed Consent

Thank you for calling today. The Cancer Information Service can provide you with information and free materials about understanding your risk for inherited cancer. I can share information over the phone, as well as send you materials that you might find helpful. You may also be interested in participating in a special research study we are conducting. We are working to improve our services and to tailor our information to women calling with concerns about inherited breast/ovarian cancer. To do so, we are currently evaluating two different approaches to providing information about inherited risk, genetic testing and risk assessment. Participation in this study is completely voluntary and all your answers will be confidential. Only the researchers will have access to the information you provide, which will be stored in a secure computer file. We will certainly provide appropriate information and materials should you decide not to participate. Participation would require two things on your part: First, you would agree to be randomly chosen for one of two educational programs. Second, you would need to agree to participate in a telephone interview that would help us to compare the effectiveness of these two programs and get your reactions to the material. Questions would be answered over the phone today, and then at three time points in the future—two weeks, two months and then six months from now. Today's interview will take anywhere from fifteen to thirty minutes depending on any questions you might have. Subsequent interviews should take no more than fifteen minutes. You may refuse to answer any questions and can withdraw at any time. There is little risk involved in answering these questions and what we learn from your responses will help our service improve the way we deliver information about inherited cancer risk, risk assessment and genetic testing services. Would you be willing to participate in this evaluation?

☐ (1) **YES**, agree
☐ (2) **NO**, do not agree— **Complete CIS Electronic Call Record Form, demographic information and then go to standard counseling**

Before we get started with the information that you are requesting, we need to get your name, address and telephone number so we can send you materials and call you in a few weeks. Please be assured that all information provided by you will be kept strictly confidential.

Contact Information

First name _____

Last name _____

Address_____

City _____ State _____ Zip Code _____

Country _____

Phone Number ( ) _____ - _____

When is the best time to reach you?

☐ Morning ☐ Afternoon ☐ Early Evening

Is there another number where we can reach you?

(_____) _____ - _____

☐ Relative ☐ Work ☐ Other

Randomization: Use last number of phone number to randomize

☐ Standard Counseling (Odd Numbers: 1,3,5,7,9)

☐ Enhanced Counseling (Even Numbers: 0,2,4,6,8)

Appendix H

FOLLOW-UP ASSESSMENT TOOL - 2 Weeks

ECRF _____ Today's Date _____ Initial Survey Date _____ Start time of call _____

First Name _____ Last Name _____

Address_____ City _____ State ___ Zip Code _____

Subject ID: _____ Subject's Age _____ Subject's Race _____

Breast Cancer _____ Ovarian Cancer _____ Both_____

CIS Introduction: "Hello, may I speak to _____. (IF PERSON IS THERE, CONTINUE; IF NOT CALL BACK OR RESCHEDULE CALL). My name is _____ and I am a representative of the Fox Chase Cancer Center. I am calling as a follow up to a phone call you made to the Cancer Information Service. When you called the CIS, a few weeks ago, you agreed to participate in a study that examines different approaches to providing information to women about breast cancer risk, risk assessment/genetic testing. To help us evaluate our service, we would like to ask you to participate in a brief, 10 minute, interview which will assess your specific thoughts, feelings, and behaviors concerning your genetic risk for breast/ovarian cancer."

"Would now be a good time to ask you a few questions?"

___YES → move to Questions

___ NO → reschedule call

"When would you like to reschedule this interview?"

Day: _____ Time: _____

Follow-up Assessment Tool: "We would just like to ask you a few questions about your thoughts and feeling concerning risk assessment/genetic testing".

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

9	8	9
don't know	refused	missing

d.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

9	8	9
don't know	refused	missing

2.) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

9	8	9
don't know	refused	missing

d.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

d.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

8) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

d.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

9) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say... **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

d.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....

To what degree would you agree with the following statements:

6. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can make decisions about pursuing risk reduction approaches, such as surgery and/or medications (e.g., tamoxifen)?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

7. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can determine if you need to increase screening, such as mammography or transvaginal ultrasounds.

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

8. Risk assessment/genetic testing can jeopardize your insurance coverage?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

9. Risk assessment/genetic testing can have a negative emotional impact on you and on your family?

1	2	3	4
strongly disagree	mildly disagree	Mildly agree	strongly agree

10. Breast Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment/genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment/genetic testing is that, finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment/genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who doesn't have an altered BRCA1 gene can still get cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

11. At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment/genetic testing for breast and ovarian cancer?

1. Very knowledgable

2. Somewhat knowledgable
3. Not very knowledgable
4. Not at all knowledgable

12. How would you describe your present behavior with regard to risk assessment and genetic testing for breast and ovarian cancer?

1. I have undergone risk assessment and genetic testing in the past 6 months (go to question 14)
2. I am planning to undergo risk assessment and genetic testing in the next 30 days (continue)
3. I am planning to undergo risk assessment and genetic testing in the next 6 months (continue)
4. I am thinking about undergoing risk assessment and genetic testing, but I'm not really sure and have
   made no specific plan (continue)
5. I am not thinking about undergoing risk assessment and genetic testing (continue)

13. If you decided to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

14. If you have already pursued risk assessment services, how prepared did you feel?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

15. How satisfied do you feel with the information you received on the phone from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not_____

_____

_____

16. How satisfied do you feel with the information you received by mail from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not_____

_____

17. To what extent would you recommend that others contact the Cancer Information Services for this information?

definitely not	Probably not	maybe	probably	definitely
1	2	3	4	5

Why or why not_____

18. Was there anything particularly helpful about the information you received from the CIS, either by mail or over the phone? Please explain_____

19. Have you ever been diagnosed with benign breast disease?

(1) ☐ Yes (2) ☐ No (7) ☐ Don't know (8) ☐ Refused (9) ☐ Missing

20. Have you ever had a breast biopsy? (1) ☐ YES (2) ☐ NO (7) ☐ Don't know (8) ☐ Refused (9) ☐ Missing

If YES: How many biopsies have you had? _____

21. Have you ever had a biopsy diagnosed as atypical hyperplasia? YES NO

22. Have you ever been diagnosed with ductal carcinoma in situ or lobular carcinoma in situ?

YES NO

23. At what age did you first start menstruating? _____ (97) ☐ don't know (98) ☐ refused
(99) ☐ missing

24. Have you stopped menstruating? Yes (answer question 25)
No (go to question 26)

25. At what age did you stop menstruating? _____ (97) ☐ don't know (98) ☐ refused
(99) ☐ missing

26. Do you have any children? (1) ☐ Yes (2) ☐ No (7) ☐ Don't know

(8) ☐ Refused (9) ☐ Missing

If YES: How old were you when your first child was born? _____ (98) ☐ Refused (99) ☐ Missing
How many children do you have?_____ (98) ☐ Refused (99) ☐ Missing

27. How many of your first degree relatives – mother, sister(s), and/or daughter(s) – have been diagnosed with breast cancer? _____

28. How many of your first degree relatives – mother, sister(s) and/or daughter(s) – have been diagnosed with ovarian cancer? _____

29. How often do you perform Breast Self Exam (BSE)?

____ more than once a week
____ at least once a week
____ a couple of times a month
____ at least once a month
____ a few times each year
____ at least once a year
____ almost never
____ never

30. How often do you go for mammograms?

____ once every few months
____ a couple of times each year
____ once a year
____ once every few years
____ almost never
____ never

31. **(For ovarian cancer callers only):** In the past six months:
How many transvaginal ultrasounds have you had? _____
How many pelvic exams have you had? _____
How many CA 125 blood test have you had? _____

32. Lastly, I will read to you 4 scenarios, each followed by statements describing what you might do in each situation. Please pick as many or as few statements as you like.

1. Vividly imagine that you are **afraid** of the dentist and have to get some dental work done. Which of the following would you do? Check **all** of the statements that might apply to you.

___ Would you ask the dentist exactly what he was going to do.
___ Would you take a tranquilizer or have a drink before going.
___ Would you try to think about pleasant memories.
___ Would you want the dentist to tell you when you would feel pain.
___ Would you try to sleep.
___ Would you watch all the dentist's movements and listen for the sound of the drill.
___ Would you watch the flow of water from your mouth to see if it contained blood.
___ Would you do mental puzzles in your mind.

2. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check **all** statements that might apply to you.

___ Would you sit by yourself and have as many daydreams and fantasies as you could.
___ Would you stay alert and try to keep yourself from falling asleep.

___ Would you exchange life stories with the other hostages.
___ If there was a radio present, would you stay near it and listen to the bulletins about what the police were doing.
___ Would you watch every movement of your captors and keep an eye on their weapons.
___ Would you try to sleep as much as possible.
___ Would you think about how nice it's going to be when you get home.
___ Would you make sure you knew where every possible exit was.

3. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check **all** of the statements that might apply to you.

___ Would you talk to your fellow workers to see if they knew anything about what the supervisor's evaluation of you said.
___ Would you review the list of duties for your present job and try to figure out if you had fulfilled them all.
___ Would you go to the movies to take your mind off things.
___ Would you try to remember any arguments or disagreements you might have had with the supervisor that would have lowered his opinion of you.
___ Would you push all thoughts of being laid off out of your mind.
___ Would you tell your spouse that you'd rather not discuss your chances of being laid off.
___ Would you try to think which employees in your department the supervisor might have thought had done the worst job.
___ Would you continue doing your work as if nothing special was happening.

4. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check **all** of the statements that might apply to you.

___ Would you carefully read the information provided about safety features in the plane and make sure you knew where the emergency exits were.
___ Would you make small talk with the passenger beside you.
___ Would you watch the end of the movie, even if you had seen it before.
___ Would you call for the stewardess and ask her exactly what the problem was.
___ Would you order a drink or tranquilizer from the stewardess.
___ Would you listen carefully to the engines for unusual noises and watch the crew to see if their behavior was out of the ordinary.
___ Would you talk to the passenger beside you about what might be wrong.
___ Would you settle down and read a book or magazine or write a letter.

Thank you for taking the time to talk with us today. We will be calling back in a month or so to ask you some additional questions. We appreciate your assistance.

End time of call _____

Appendix I

FOLLOW-UP ASSESSMENT TOOL – 2-6 Months

ECRF _____ Today's Date _____ Initial Survey Date _____ Start time of call _____

First Name _____ Last Name _____

Address_____ City _____ State ___ Zip Code _____

Subject ID: _____ Subject's Age _____ Subject's Race _____

Breast Cancer _____ Ovarian Cancer _____ Both_____

CIS Introduction: "Hello, may I speak to _____. (IF PERSON IS THERE, CONTINUE; IF NOT CALL BACK OR RESCHEDULE CALL). My name is _____ and I am a representative of the Fox Chase Cancer Center. I am calling as a follow up to a phone call you made to the Cancer Information Service. When you called the CIS, a few weeks ago, you agreed to participate in a study that examines different approaches to providing information to women about breast cancer risk, risk assessment/genetic testing. To help us evaluate our service, we would like to ask you to participate in a brief, 10 minute, interview which will assess your specific thoughts, feelings, and behaviors concerning your genetic risk for breast/ovarian cancer."

"Would now be a good time to ask you a few questions?"

___YES → move to Questions

___ NO → reschedule call

"When would you like to reschedule this interview?"

Day: _____ Time: _____

Follow-up Assessment Tool: "We would just like to ask you a few questions about your thoughts and feeling concerning risk assessment/genetic testing".

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

10	8	9
don't know	refused	missing

e.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

10	8	9
don't know	refused	missing

e.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

e.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

10) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

e.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

11) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say... **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

e.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

To what degree would you agree with the following statements:

6. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can make decisions about pursuing risk reduction approaches, such as surgery and/or medications (e.g., tamoxifen)?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

7. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can determine if you need to increase screening, such as mammography or transvaginal ultrasounds.

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

8. Risk assessment/genetic testing can jeopardize your insurance coverage?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

9. Risk assessment/genetic testing can have a negative emotional impact on you and on your family?

1	2	3	4
strongly disagree	mildly disagree	Mildly agree	strongly agree

10. Breast Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment/genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment/genetic testing is that, finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment/genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who doesn't have an altered BRCA1 gene can still get cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

11. At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment/genetic testing for breast and ovarian cancer?

4. Very knowledgeable
5. Somewhat knowledgeable
6. Not very knowledgeable
4. Not at all knowledgeable

12. How would you describe your present behavior with regard to risk assessment and genetic testing for breast and ovarian cancer?

6. I have undergone risk assessment and genetic testing in the past 6 months (go to question 14)
7. I am planning to undergo risk assessment and genetic testing in the next 30 days
8. I am planning to undergo risk assessment and genetic testing in the next 6 months
9. I am thinking about undergoing risk assessment and genetic testing, but I'm not really sure and have made no specific plan
10. I am not thinking about undergoing risk assessment and genetic testing

13. If you were given the opportunity to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

14. How prepared did you feel when you under went these procedures?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

15. How satisfied do you feel with the information you received on the phone from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not_____

_____

_____

16. How satisfied do you feel with the information you received by mail from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not_____

_____

17. To what extent would you recommend that others contact the Cancer Information Services for this information?

definitely not	Probably not	maybe	probably	definitely
1	2	3	4	5

Why or why not_____

18. Has the information you received from the Cancer Information Service changed your thinking in regards to your personal risk for breast/ovarian? YES No

If YES. In what way?_____

19. Has the information you received from the Cancer Information affected your decision to pursue risk assessment/genetic testing? YES No
If YES. In what way?_____

20. Have you looked for more information on breast/ovarian cancer or risk assessment/genetic testing, since your call to the Cancer Information Service? YES NO
If YES. Where? _____

21. Is there any information that you are now aware of that you wish you had received during your call to the Cancer Information Service? YES NO

If YES. What is that information?_____

22. Have you discussed your family history with other family members? YES NO

23. Have you attempted to locate your family members medical records in order to confirm diagnosis?
YES NO

24. Have you discussed your concerns about cancer with your health care provider?
(1) ☐ Yes (2) ☐ No

25. How often do you perform Breast Self Exam (BSE)?

____ more than once a week
____ at least once a week
____ a couple of times a month
____ at least once a month
____ a few times each year
____ at least once a year
____ almost never
____ never

26. How often do you go for mammograms?

____ once every few months
____ a couple of times each year
____ once a year
____ once every few years
____ almost never
____ never

27. **(For ovarian cancer callers only):** In the past six months:

How many transvaginal ultrasounds have you had? _____
How many pelvic exams have you had? _____
How many CA 125 blood test have you had? _____

(2-Month Follow-Up) *In a few months, we will be calling one last time. The interview will be very brief. We thank you for helping with this research project.*

(6-Month Follow-Up) *Thank you for taking the time to talk with us today. This interview concludes your participation in this research study. We appreciate your assistance. Thank you for your participation.*

End time of call _____